510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K071852

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AUG 29 2007

Trade Name: APS-System

Common/Usual Name: Autodynamic Plate-Screw System

Classification Name: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component

Device Class: Class II

Product Code: 87 KTT

Classification: CFR Chapter I, Title 21 § 888.3030

Review Panel: Orthopaedics

Performance Standards:

- Devices are manufactured according to cGMP's, applicable ASTM requirements, and applicable harmonised standards ISO 13485:2003.
- The implants of the APS-System are manufactured from Titanium Alloy (Ti 6Al 4V E.L.I. = ASTM F136 or ISO 5832-3), and 316L Stainless Steel (ASTM F 138 or ISO 5832-1).
- The APS-System accessories incorporate surgical grade Stainless Steel (complying with ASTM F899-02, ASTM F1586-02), Silicone, Propylux and Polyoxymethylene.
- ASTM F382-99: Standard Specification and Test Method for Metallic Bone Plates.

Intended Use:

The *aap* APS System is intended for use of fractures of femoral head (Hip Plates) and condylar part of the femur (Condylar Plates).

Specific indications, which are dependent in the angle of the plate, include:

- 125°-150°: fractures of the trochanter region, simple and multifragmentary pertrochanteric, intertrochanteric
- 95°: distal and intercondylar fractures of the femur

Contraindications

Inflammation, sepsis and osteomyelitis are absolute contraindications.

All applications that are not defined by the indications and the specialist literature are contraindicated.

In addition, surgical success can be adversely affected by:

- acute or chronic infections, local or systemic
- vascular, muscular or neurological pathologies that compromise the concerned extremity
- all concomitant pathologies that could affect the function of the implant.
- osteopathies with reduced bone substance such as severe osteoporosis
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment.
- Known or suspected sensitivity to metal
- Corpulence: an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur.
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status.

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- the presence of tumors
- congenital abnormalities
- immunosuppressive pathologies
- increased sedimentation rates that cannot be explained by other pathologies
- increased leukocyte (WBC) count
- pronounced left shift in the differential leukocyte count.
- Untreated malfunction of the metabolism
- Joint destruction caused by haemophilia, tabes or after infections
- Instability of the joint ligaments

Device Description:

The implants for the *aap* APS System are manufactured of Titanium Alloy and Stainless Steel and are available for the femoral head and the condylar part of the femur. The titanium alloy and the stainless steel material is identical to the materials used in the predicate devices.

The *aap* System includes APS Plates with various angles (95° for condylar plates; 125°, 130°, 135°, 140°, 145° and 150° for Hip Plates), APS Lag Screws with various lengths from 50mm to 145mm, APS compression screws and instruments for implantation.

Predicate Devices for Substantial Equivalence:

The APS-System is similar in size, material and intended use to the

- Synthes Dynamic Hip Screw (DHS) System (K791619),
- Synthes Dynamic Condylar Screw (DCS) System (K840954),
- DePuy ACE TK2 Hip Screw System (K972629),
- Precimed Hip Screw System (K023851),
- Corifix Dynamic Hip Screw System (K973231)

Comparision of the technological Characteristics of the device to the predicate legally marketed devices:

There are no significant differences between the APS-System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, materials and intended use.

Sterilisation Information:

The devices are distributed in non sterile, recommendations for sterilization are contained in package insert. Note: These devices are sterilised by end users utilizing the approved/outlined guidelines found in the AAMI Guideline "Good Hospital Practice: Steam Sterilisation and Sterility Assurance" and in ANSI/AAMI/ISO 11737 guidelines to achieve the acceptable Sterility Assurance Level (SAL).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aap Implantate AG
% Dipl.-Ing. Marc Seegers
Director Quality Management
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AUG 29 2007

Re: K071852
Trade/Device Name: APS-System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: June 29, 2007
Received: July 5, 2007

Dear Mr. Seegers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: APS System

Indications for Use:

- 125°-150° Hip Plate: fractures of the trochanter region, simple and multifragmentary pertrochanteric, intertrochanteric
- 95° Condylar Plate: distal and intercondylar fratures of the femur

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071852